

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4988. Aqueous extract of pituitary anterior and ovarian. (F. D. C. No. 37547. S. Nos. 5-695/6 M.)

QUANTITY: 82 cartons, 25 2-cc. ampuls each, and 362 30-cc. vials at Evanston, Ill.

SHIPPED: Between 10-15-54 and 12-10-54, from Rensselaer, N. Y., by Winthrop-Stearns, Inc.

LABEL IN PART: (Ampul) "2 cc size Sterile Aqueous extract of Pituitary Anterior and Ovarian With procaine hydrochloride 1% and chlorobutanol"; (vial) "Multidose Vials - Sterile Aqueous extract of Pituitary Anterior - Ovarian * * * Each cc contains water soluble extractives from 5 gr. of Anterior Pituitary and 20 gr. of Ovarian Tissue with procaine HCl 1% in isotonic salt solution with chlorobutanol - George A. Breon and Company, New York 18, NY."

ACCOMPANYING LABELING: Leaflets entitled "[For Physicians' Information] The Administration of Aqueous Anterior Ovarian Substances."

LIBELED: 1-10-55; amended 7-20-55, N. Dist. Ill.

CHARGE: 502 (a)—the accompanying labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for menopausal nervous instability, essential amenorrhea, and dysmenorrhea; and 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: George A. Breon & Co., claimant, New York, N. Y., filed answers to the libel and to the amended libel, denying that the product was misbranded as alleged. On 8-11-55, interrogatories were served upon the claimant by the Government. The claimant withdrew its answer; and, on 10-5-55, the court entered a default decree of condemnation and destruction.

4989. Alberty products. (F. D. C. No. 36439. S. Nos. 83-633/7 L, 83-639/41 L.)

QUANTITY: 14 12-oz. btls., of *Alberty Phar-Oil*, 13 180-tablet pkgs. of *Alberty Special Formula tablets*, 9 200-tablet btls. and 57 475-tablet btls. of *Alberty Phloxo B tablets*, 6 200-pellet btls. and 21 475-pellet btls. of *Alberty's Lebara No. 2 pellets*, 29 3-lb cans and 54 12-oz. cans of *Instant Alberty Food*, 8 124-tablet btls. and 4 275-tablet btls. of *Ri-Co tablets*, 15 50-perle btls. and 3 350-perle btls. of *Alberty Garlic and Vegetable Oil Perles*, and 1 225-pellet btl. and 4 500-pellet btls. of *Alberty's Sabinol pellets* at Des Moines, Iowa.

SHIPPED: Between 7-2-53 and 1-25-54, from Hollywood, Calif., by Alberty Food Products.

LABEL IN PART: (Btl.) "Alberty Phar-Oil * * * A Dietary Food Supplement Ingredients: Cod Liver Oil, Wheat Germ Oil, Linseed Oil."

(Pkg.) "Alberty New Improved Special Formula Tablets A Dietary Supplement Ingredients: Kelp, DiCalcium Phosphate, Iron (ferrous) Gluconate, Copper Peptonate, Mixed Tocopheral Concentrate, Manganese Sulfate, Pantothenol, Para-Aminobenzoic Acid. In a base of Yeast, Liver Extract, Orchic

*See also No. 4986.